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TRANSMITTAL OF APPEAL BRIEF (Small Entity)

Docket No.
BAF-14802/29

In Re Application Of: Ferree

Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
10/657,914	09/09/2003	P. Prebilit	25006	3738	5106

Invention: **BIORESORBABLE COMPONENTS AND METHODS FOR SPINAL ARTHROPLASTY**

COMMISSIONER FOR PATENTS:

Transmitted herewith is the Appeal Brief in this application, with respect to the Notice of Appeal filed on:

April 3, 2006

☒ Applicant claims small entity status. See 37 CFR 1.27

The fee for filing this Appeal Brief is: **\$250.00**

☒ A check in the amount of the fee is enclosed.

☐ The Director has already been authorized to charge fees in this application to a Deposit Account.

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[Handwritten Signature]

Signature

Dated: **June 5, 2006**

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I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on

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Signature of Person Mailing Correspondence

Sheryl Hammer

Typed or Printed Name of Person Mailing Correspondence

CC:



THE UNITED STATES PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of: Ferree

Serial No.: 10/657,914

Group No.: 3738

Filed: Sept. 9, 2003

Examiner: P. Prebilio

For: BIORESORBABLE COMPONENTS AND METHODS FOR SPINAL ARTHROPLASTY

APPELLANT'S BRIEF UNDER 37 CFR §1.192

Mail Stop Appeal Brief
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I. Real Party in Interest

The real party and interest in this case is Dr. Bret A. Ferree, Applicant and Appellant.

II. Related Appeals and Interferences

There are no appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. Status of Claims

The present application was filed with 8 claims. Claims 9-20 were added by amendment. Claims 9 and 10 have been canceled in previous amendments. Claims 11-20 have been canceled by amendment attached to this Brief. Claims 1-8 are pending, rejected and under appeal. Claim 1 is the sole independent claim.

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**IV. Status of Amendments Filed Subsequent
Final Rejection**

An after-final amendment has been filed canceling claims 11-20. The Appendix A, Claims on Appeal section of this Brief reflects this amendment.

V. Summary of Claimed Subject Matter

Independent claim 1 is directed to an improved spinal arthroplasty apparatus, comprising one or more bio-resorbable components located outside of an intradiscal space to retain and temporarily limit the motion of an artificial disc replacement (ADR) within the intradiscal space until soft tissues surrounding the spine heal. (Specification, page 3, lines 3-19).

VI. Grounds of Objection/Rejection To Be Reviewed On Appeal

A. The rejection of claims 1-7 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,019,792 to Cauthen.

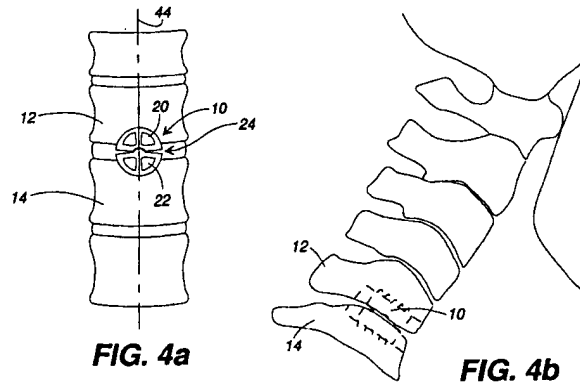
B. The rejection of claim 8 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,019,792 to Cauthen in view of U.S. Patent No. 6,096,080 to Nicholson et al.

VII. Argument

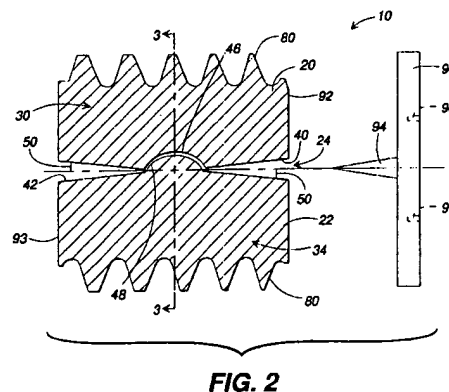
A. The rejection of claims 1-7 wherein claims 2-7 stand or fall with claim 1.

Claim 1 stands rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,019,792 to Cauthen. Claim 1 resides in improved spinal arthroplasty apparatus comprising "one or more bio-resorbable components located outside of an intradiscal space to retain and temporarily limit the motion of an artificial disc replacement (ADR) within the intradiscal space until soft tissues surrounding the spine heal." It is the Examiner's position that the endcaps (90) of Cauthen anticipate "since the assembled device of Cauthen is capable of being assembled and 'located outside an intradiscal space'." Appellant disagrees.

First, the *assembled device* of is not "located outside an intradiscal space." Rather, the assembled device of Cauthen is located *within* an intradiscal space. Figure 4a and 4b of Cauthen, reproduced below, shows the position of the implant 10. As clearly depicted in Figure 4b, the implant is essentially centered in the anterior vertebral column, as one of skill in the art would expect for load-bearing purposes.



Although the endcaps (90) are not shown in Figure 4, they are shown in Figure 2 of Cauthen, also reproduced below:



As is evident from this Figure, the endcaps (90) are relatively thin caps that go onto the ends 92, 93 of the implant. To one of skill in the art, they, too, would be situated within the intradiscal space. There is no teaching or suggestion whatsoever in Cauthen that the endcaps (90) would be located outside of the intradiscal space after the device is installed. Anticipation may be established only when a single prior art reference discloses, expressly or under principles of inherency, each and every element of a claimed invention. *RCA Corp. v. Applied Digital Data Systems*, 730 F.2d 1440, 1444, 221 USPQ 385, 388 (Fed. Cir. 1984). Moreover, anticipation requires the presence of all elements of a claimed invention as arranged in the claim, such that a disclosure "that 'almost' meets that standard does not 'anticipate'." *Connell v. Sears, Roebuck Co.*, 722 F.2d 1542, 1548, 220 USPQ 193, 198 (Fed. Cir.

1983). Since Cauthen does not disclose a bio-resorbable component located outside of an intradiscal space, the reference does not anticipate.

Second, Appellant's recitation that the component(s) "retain and temporarily limit the motion of an artificial disc replacement (ADR) within the intradiscal space" should be taken into consideration in conjunction with claim interpretation. Even if considered functional, the language must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used. In *Innova/Pure Water Inc. v. Safari Water Filtration Sys. Inc.*, 381 F.3d 1111, 1117-20, 72 USPQ2d 1001, 1006-08 (Fed. Cir. 2004), the court noted that the claim term "operatively connected" is "a general descriptive claim term frequently used in patent drafting to reflect a functional relationship between claimed components," that is, the term "means the claimed components must be connected in a way to perform a designated function." "In the absence of modifiers, general descriptive terms are typically construed as having their full meaning." *Id.* at 1118, 72 USPQ2d at 1006. In the patent claim at issue, "subject to any clear and unmistakable disavowal of claim scope, the term 'operatively connected' takes the full breath of its ordinary meaning, i.e., 'said tube [is] operatively connected to said cap' when the tube and cap are arranged in a manner capable of performing the function of filtering." *Id.* at 1120, 72 USPQ2d at 1008.

The instant situation is nearly identical. Appellant is claiming a "one or more bio-resorbable components located outside of an intradiscal space to retain and temporarily limit the motion of an artificial disc replacement (ADR) within the intradiscal space..." Not only does Cauthen fail to disclose or suggest "one or more bio-resorbable components located outside of an intradiscal space," Cauthen does not disclose or suggest "one or more bio-resorbable components located outside of an intradiscal space" for the purpose of "retain[ing] and temporarily limit[ing] the motion of an artificial disc replacement (ADR) within the intradiscal space." Thus anticipation has not been established.

B. The rejection of claim 8.

Claim 8 stands rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,019,792 to Cauthen in view of U.S. Patent No. 6,096,080 to Nicholson et al. Given that Cauthen's spinal implant is essentially a cylindrical dowel-type unit including a ball-and-socket joint, there is no teaching or suggestion from the prior art to utilize allograft material. Despite the teachings of Nicholson

et al., it is well-settled that, in rejecting claims under 35 U.S.C. §103, the Examiner must provide a reason why one having ordinary skill in the pertinent art would have been led to combine the cited references to arrive at Applicant's claimed invention. The "Examiner's position" does not set forth the standard. Rather, there must be something *in the prior art* that suggests the proposed combination, other than the hindsight gained from knowledge that the inventor choose to combine these particular things in this particular way. *Uniroyal Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1051, 5 USPQ2d 1434, 1438 (Fed. Cir. 1988). The Examiner is also required to make specific findings on a suggestion to combine prior-art references. *In Re Dembiczak*, 175 F.3d 994, 1000-01, 50 USPQ2d 1614, 1617-19 (Fed. Cir. 1999). Such findings have not been articulated. Since *prima facie* obviousness requires factual evidence, the subject claim is allowable under 35 U.S.C. §103.

Conclusion

In conclusion, for the arguments of record and the reasons set forth above, all pending claims of the subject application continue to be in condition for allowance and Appellant seeks the Board's concurrence at this time.

Respectfully submitted,

By: _____

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Date: June 5, 2006

APPENDIX A**CLAIMS ON APPEAL**

1. Improved spinal arthroplasty apparatus, comprising:
one or more bio-resorbable components located outside of an intradiscal space to retain and temporarily limit the motion of an artificial disc replacement (ADR) within the intradiscal space until soft tissues surrounding the spine heal.
2. The improvement of claim 1, wherein the bio-resorbable components include a rod, plate, screw, or a combination thereof.
3. The improvement of claim 1, wherein the bio-resorbable components facilitate a limited degree of motion or mobility during or after healing.
4. The improvement of claim 3, wherein the limited degree of motion or mobility is controlled by the flexibility of the bioresorbable components.
5. The improvement of claim 4, wherein the flexibility of the bio-resorbable components is due in part to the modulus of elasticity of the bioresorbable components.
6. The improvement of claim 4, wherein the flexibility of the bio-resorbable components is due in part to the thickness or other physical attribute of the bioresorbable components.
7. The improvement of claim 3, wherein the limited degree of motion or mobility is controlled by the rate of resorbtion of the bio-resorbable components.
8. The improvement of claim 1, further including an allograft ADR.

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APPENDIX B

EVIDENCE

None.

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APPENDIX C
RELATED PROCEEDINGS

None.